



U.S. ENVIRONMENTAL PROTECTION AGENCY

**Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460**

EPA

Reg.Number:

53883-352

Date of Issuance:

9/9/2014

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Prefurred Plus IGR for Cats

Name and Address of Registrant (include ZIP Code):

Control Solutions, Inc.
5903 Genoa Red Bluff Rd
Pasadena, TX 77507

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(C)(7)(a) provided that Control Solutions, Inc.:

1) Submit and/or cite all data required for registration/reregistration review of your product when the Agency requires all registrants of similar products to submit data. Failure to submit acceptable data to fulfill these requirements may result in registration cancellation in accordance with FIFRA section 6(e).

SEE NEXT PAGE FOR ADDITIONAL COMMENTS

Signature of Approving Official:
Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505P)

Date: 09/09/2014

2) This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on September 9, 2016.

3) If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

4) Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.

5) You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning October 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager. The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
- Product name (brand name)
- Lot #
- Where purchased: Internet, store, veterinarian.
- Active ingredient(s)
- Weight range for product

- Date on which incident occurred. (mm/dd/yyyy)
- State in which the incident occurred. (Standard 2 letter abbreviation)
- Registrant case #

- Species: Dog, cat, other (specify).
- Breed: (As reported by pet owner)
- Age: Months or years.
- Sex: M, F, or neutered.
- Weight: Pounds.

- Primary Route of Exposure: Dermal, oral, other animal, inhalation, other.
- Body System: Neurological, dermatological, GI, respiratory, ocular, other.
- Major signs noted with separate column for each sign, using standard terminology.
- Time to Onset: (Hours, days)
- Treated by veterinarian: Yes or No
- First time product used: Yes or No
- Misuse: Use on incorrect species, overdose, too frequent dosing, other (describe).
- Any known pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.

6) Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported, including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- Summary table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each cat breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
- 7) Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.
- 8) Submit one (1) copy of the revised final printed label before the product is released for shipment.
- 9) Submit and/or cite all data required for reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data. See the data requirements in DCI ID# GDCI-129121-1305 issued March 14, 2013 for fipronil. For information on the DCI's you may contact Susan Barstow in the OPP Product Re-evaluation Division at 703-603-0065 or by email at bartow.susan@epa.gov.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any comments or concerns, please contact Carlyn Petrella via telephone at 703-347-0439 or by email at petrella.carlyn@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: September 9, 2014

CSI Master Label

Information in [] is optional
Information in { } is a note to the reviewer

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{ CARTON LABEL - DRAFT MASTER LABEL COPY }

{ Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change. }

Prefurred Plus IGR for Cats



{ ABNs: }

[FLEE™ Plus IGR for Cats]

[For use ONLY on cats [[&] [and] kittens] over 1.5 lbs and over 8 weeks of age] [OR]
[Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs]

[Apply to kittens over 8 weeks old]
[Apply to kittens 8 weeks or older]

{ Mosquitoes }

[Kills mosquitoes within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

{ Chewing Lice }

[Kills chewing lice]
[Rapid elimination of chewing lice infestation]
[Fast Action against chewing lice infestations]

{ Adult Fleas }

[Kills adult fleas [for up to six weeks]]
[Kills Fleas [Up to [4] [6] weeks]!]
[Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

{ Ticks }

[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

{ Multiple Infestations }

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]
[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
[Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]]
[Breaks the Flea Life Cycle]
[Monthly flea, tick, [mosquito,] chewing lice, and flea egg protection]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice]
[[Seven] [7] [Six] [6] Way [Action] [Effectiveness] [Control] [kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae and prevents the development of flea pupae]]
[[Six] [6] [Five] [5] Way [Action] [Effectiveness] [Control] [kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs & flea larvae]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

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[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand name][this product] monthly to break the flea life cycle.]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick and Chewing Lice Control]
[Use [Brand name][This product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[[4 week] [1 month] [30 day] Flea and Tick Treatment!]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]]
[Brand name][This product provides convenient and effective flea, tick, [and] chewing lice [and] [mosquito]
control for cats and kittens over 8 weeks of age]
[Controls reinfestation [on your cat](#) of fleas for up to six weeks]

{Flea Eggs and Larvae}

[Controls flea reinfestation [on your cat](#) {for up to six weeks}]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]]
[Kills all stages of the flea (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If cat is at high risk for flea reinfestation apply once a month]
[Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks]
[With (S)-methoprene [Insect Growth Regulator] [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With [Insect Growth Regulator] [IGR] to Break Flea Life Cycle]
[Dual Action (!): Fipronil with (S)-methoprene [insect growth regulator] [IGR] Effectively Breaks the Flea
Life Cycle]
[Dual Action (!): Effectively Breaks the Flea Life Cycle(!)]
[Kills Flea Eggs & Flea Larvae [for up to six weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]

{All Others}

[For Cats and Kittens 8 weeks of age or older]
[Can be used on kittens 8 weeks of age and older]
[Specially Formulated for Cats and Kittens Over 8 Weeks Old]
[Fast Acting] [Long Lasting]
[Easy to Use [Application]]
[Best if used year round!]
[Apply monthly]
[Once a month treatment]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six
Applications][Twelve Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month
Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4
Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48
Week Supply][52 Week Supply][104 Week Supply]
[Waterproof]
[Effective even after bathing]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]
[[Free] Calendar Stickers Inside!]
[Monthly application reminder inside]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [inside]]

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Contains fipronil and (S)-methoprene, the active ingredients used in FRONTLINE® Plus for Cats. FRONTLINE® is a registered trademark of Merial. Prefurred Plus IGR for Cats is not manufactured, or distributed by Merial, seller of FRONTLINE® Plus for Cats.

[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]]
[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil	9.80%
(S)-methoprene	11.80%
OTHER INGREDIENT:	<u>78.40%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See[Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.017 fl oz (0.50 mL) applicator(s)]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

{**END - FRONT PANEL**} {**START – BACK/SIDE PANEL**}

[[Brand name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas (all stages) and ticks [(including those that may transmit Lyme disease)]. [The active ingredients in [Brand name][this product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] on cats only.]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, or aged cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID

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If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not double-dose cats. Use entire contents of tube vial on each cat. [Do not split one tube between two cats.] Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{Outer Packaging}

How to open: Remove product tube(s) [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the tube [vial] and use the narrow end to part the cat's hair. Apply contents of one tube [vial] of [Brand name][This product] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the tube [vial] in paper and put into the trash. Only one applicator per treatment is needed.

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FREQUENCY OF APPLICATION

Use [Brand name][this product] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [Brand name][this product] kills adult fleas for up to six weeks. Apply monthly if your cat is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand name][This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks]. [[Brand name][This product] can be used on breeding, pregnant and lactating (queens) (female cats).]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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[[WARRANTY]

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.]

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX]

[For more information]

[Non-Emergency, call XXX-XXX-XXXX]

[Made in USA]

Distributed by:
Control Solutions, Inc.
5903 Genoa-Red Bluff Road
Pasadena, TX 77507

EPA Reg. No. 53883-NEW
EPA Est. No. XXXXX-XX-XXX

{END - BACK/SIDE PANEL}

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{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE }

{How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.}

[Application Instructions] [Directions for Use]

How to Open:

1. Remove product tube(s) [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube over cat and use open end to part cat's hair.
2. Apply contents of one tube [vial] of {Brand Name} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze tube firmly to apply all of the solution to the cat's skin.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[Monthly reminder card]

[3 Month [Treatment] [Application] Tracker]

[For year round protection apply [Brand name][This product] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[calendar stickers with [Brand name][This product] [Place stickers on your calendar as a reminder to reapply [Brand name][This product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand name][This product] . Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

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{Optional graphics below may or may not appear anywhere on finished label}

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	



[Flea life cycle diagram] [Flea Life Cycle]

{END - OPTIONAL PACKAGE COPY}

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{START – TUBE/VIAL LABEL}

{Front Label}	{Back Label}
{Brand Name} For Cats over 1.5 lbs \geq 8wks Fipronil 9.8%, (S)-methoprene 11.8% 0.017 fl oz {label code}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 53883-NEW {label code}

{END – TUBE/VIAL LABEL}